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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,739	11/08/2001	James C. Copeland	OXR 2 0025	4971

7590 04/21/2005

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP
7th Floor
1100 Superior Avenue
Cleveland, OH 44114-2516

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,739	COPELAND ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5,7-35 are under consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2005 has been entered.

Rejections/Objections Withdrawn

1. Claims 6 and 8 (paragraph d) reject under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been obviated based upon the amendments of the claims to clarity issues raised of record.
2. Claims 1,3-5, 7-9 rejected under 35 U.S.C. 102(b) as being anticipated by Merad et al (1992), is herein withdrawn in light of independent claim 1 having been amended to recite the claim limitations of claim 6.
3. Claims 1-2,4-5 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (1984 is herein withdrawn in light of independent claim 1 having been amended to recite the claim limitations of claim 6.

Rejections Maintained

4. Claims 10-12,15-17,20, 22 rejected under 35 U.S.C. 102(b) as being anticipated by Blondin et al (US Pat. 4,808,517) for reasons of record in paper number 6, paragraph 8.

5. Claims 1-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992, English Translation) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6, # 11.

6. Claims 28-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6,#12.

Response to Arguments

7. Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive. Applicant asserts that the instantly claimed invention is not disclosed and/or remotely discussed in any of the references cited.

8. It is the position of the examiner that Blondin et al (US Pat. 4,808,517) disclose the claimed invention set forth in claims 10-12,15-17,20, 22 , specifically a composition (see Example 1, col. 7, lines 35-47 and "Cyanide, Table 1") that comprises:

(instant claims 10-12, 20) a hydrogen donating substance (sucrose and succinate (a salt of succinic acid)),

(instant claim 10 and 15) a plurality of oxygen scavenging membrane fragments (submitochondrial particles) and

(instant claims 16-17, 22) an inhibitor of electron transport (cyanide) (see Blondin, Table 1, col. 8).

9. The rejection of claims 1-35 over the combination of Merad in view of Alder et al is maintained because Merad et al describes a nutrient medium that comprises sodium azide for the purpose of isolating strict anaerobic bacteria selectively over facultative anaerobes (Proteus) and the sodium azide concentration of the medium of Merad includes the concentration recited in Applicant's claim 3 ((Conc. Recited in instant claim 3) **1 mg/ml** = 100 mg/100ml = 0.1 g/100 ml = **0.1%** sodium azide (Conc. Used and taught to be most effective by Merad et al, see English abstract last line and page 165, col. 4, "0.1%" azide)),and Adler et al also describe a nutrient medium for the selective enhancement of anaerobes in a sample, the nutrient medium comprising oxygen scavenging membrane fragments for the same purpose as Merad, selectively enriching anaerobic growth of microbes. It would have been obvious to the person of ordinary skill in the art at

the time the invention was made to modify the method of Merad et al to include the medium components of Adler, because both Merad and Adler teach methods of isolating anaerobic bacteria through the utilization of a selective anaerobic growth medium and it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Copeland et al (US Pat. 5,830,746) .

12. **Instant claims 1, 4,10, 16, 19-20, 25**: Merad teach compositions (dishes or broth, see page 4, Eng. last two paragraphs) and a method of selectively enriching anaerobes from a sample (see Materials and Methods, English translation, page 3) that contains facultative microorganisms (see title),

wherein the nutrient base medium (Columbia agar or Trypiticase yeast broth, enriched with hemin, see English translation page 4, Inhibitors section, both types of nutrient mediim) comprised sodium azide (see page 4, line 4, "NaAz").

Instant claims 2-3: wherein the concentration of the azide in the medium was 1 mg/ml (same concentration as 0.1%).

Instant claims 5, 9: wherein the medium is contained in dish or broth in a jar (see page 4, English translation (reference page 164), last two lines)

Instant claim 7: wherein the sample is obtained from patients (see English translation page 2 (original French document page 161) with infection (see lines 3-5), and Introduction lines 1-2, same page)

Instant claims 17-18, 22-27: wherein the electron transport system inhibitor is a salt of an azide (see sodium azide, "NaAz" page 4, top of page, English translation, original French document page 164)

Instant claim 8, 28-35: the method comprising the steps of:

Providing a nutrient medium (trypitcase yeast broth, page 4, translation or Columbia agar, page 4 of translation) composition that comprises a nutrient medium and azide;

Inoculating the sample into the medium compsition (see page 4 of translation)

Incubating the inoculated liquid medium composition (see page 4, translation)

Determining the presence of growth with partial growth (see page 6, paragraph 3)

Sampling for characterization of the anaerobe organism (see page 7 "confirmed the frequent association with the bacteroides and anaerobic cocci in various infections; and determined the presence or absence of each anaerobe from the mixture of anaerobes (see paragraph 3, page 6).

Merad et al show the isolation and characterization of polymicrobial samples with selective enhancement of anaerobes through incorporation of sodium azide into the growth medium, but differs from the instantly claimed invention by failing to show the growth medium to further comprise the presence of oxygen scavenging membrane fragments, the medium to be either a liquid or solid medium.

Copeland et al teach growth medium to further comprise the presence of oxygen scavenging membrane fragments, the medium being liquid medium (see col. 1, line 59; col. 6, lines 13-15) that can be solidified into an agar that comprises biocatalytic oxygen reducing agents of obtained from the cytoplasmic membranes of bacteria or mitochondrial organelles of higher non-bacterial organisms (see col. 5, lines 1-7), and may be incorporated into bags, jars, incubators or chambers (see col. 5, line 23-25) in an analogous art for the purpose of isolating anaerobes (see col. 1, lines 4-16).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the composition and method of Merad et al to include the medium components of Copeland, because both Merad and Copeland teach compositions and methods of isolating anaerobic bacteria through the utilization of a selective anaerobic growth medium and it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

13. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Fung et al (US Pat. 5,405,773).

14. **Instant claims 1, 4,10, 16, 19-20, 25**: Merad teach compositions (dishes or broth, see page 4, Eng. last two paragraphs) and a method of selectively enriching anaerobes from a sample (see Materials and Methods, English translation, page 3) that contains facultative microorganisms (see title),

wherein the nutrient base medium (Columbia agar or Trypiticase yeast broth, enriched with hemin, see English translation page 4, Inhibitors section, both types of nutrient mediim) comprised sodium azide (see page 4, line 4, "NaAz").

Instant claims 2-3: wherein the concentration of the azide in the medium was 1 mg/ml (same concentration as 0.1%).

Instant claims 5, 9: wherein the medium is contained in dish or broth in a jar (see page 4, English translation (reference page 164), last two lines)

Instant claim 7: wherein the sample is obtained from patients (see English translation page 2 (original French document page 161) with infection (see lines 3-5), and Introduction lines 1-2, same page)

Instant claims 17-18, 22-27: wherein the electron transport system inhibitor is a salt of an azide (see sodium azide, "NaAz" page 4, top of page, English translation, original French document page 164)

Instant claim 8, 28-35: the method comprising the steps of:

Providing a nutrient medium (trypitcase yeast broth, page 4, translation or Columbia agar, page 4 of translation) composition that comprises a nutrient medium and azide;

Inoculating the sample into the medium compsition (see page 4 of translation)

Incubating the inoculated liquid medium composition (see page 4, translation)

Determining the presence of growth with partial growth (see page 6, paragraph 3)

Sampling for characterization of the anaerobe organism (see page 7 "confirmed the frequent association with the bacteroides and anaerobic cocci in various infections; and determined the presence or absence of each anaerobe from the mixture of anaerobes (see table, paragraph 3, page 6).

Merad et al show the isolation and characterization of polymicrobial samples with selective enhancement of anaerobes through incorporation of sodium azide into the growth medium, but differs from the instantly claimed invention by failing to show the growth medium to further comprise the presence of oxygen scavenging membrane fragments, the medium to be either a liquid or solid medium.

Fung et al teach the addition of oxygen scavenging membrane fragments to known anaerobic growth medium (see Jepsen claims 1-3), the medium being either liquid or solid medium (see abstract) that can be solidified into an agar that comprises biocatalytic oxygen reducing agents obtained from the cytoplasmic membranes in an analogous art for the purpose of isolating anaerobes (see abstract).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the composition and method of Merad et al to include the medium components of Fung et al, because both Merad and Fung et al teach compositions and methods of isolating anaerobic bacteria through the utilization of a selective anaerobic growth medium and it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
3. Asperger et al (1999) is cited to show oxyrase added to known microbial growth mediums provides for enhanced selectivity of the medium for anaerobes.

4. Copeland et al (patents) are cited to shows devices that comprise oxyrase for the isolation of anaerobic microorganisms.
5. Various Patents are being cited to show compositions of a glucose or alcohol oxidase together with azide (5081015; 4414334; 4894339; 4810633; 4485016; 4254220; 3721607; 4430427.
6. Two patents are being cited to show an azide to be a catalase inhibitor : US Pat. 4040908 and 5871952.
7. WO92/07088 and WO88/04319 are cited to show sources for oxygen scavenging membrane fragments.
8. King (US Pat. 5,498,528) is cited to show Columbia agar to comprise corn starch a hydrogen donating substance and trypticase to comprise a pancreatic digest of casein (see Table 1, col. 5-6).
9. Mayer et al (US Pat. 5,789,191) is cited to see that addition of azide to a customary base medium for the purpose of selectively isolating enterococci.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
April 8, 2005